

The YODA Project: Developing Methods for Sharing Clinical Trial Data

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The Yale University Open Data Access (YODA) Project: Developing Methods for Sharing Clinical Trial Data

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Background

- Clinical research data sharing and transparency ensures patient and clinician access to all conducted research to understand drug/device efficacy and safety
- Maximizes the value of collected data and promotes follow-up studies of secondary research questions using existing data
- The YODA Project developed a model to facilitate access to participant-level clinical research data to promote independent analysis by external investigators
- Currently collaborating with Medtronic, Inc. and Johnson & Johnson to facilitate access to their clinical trial program data
- Project principles include:
 - Advance science and public health
 - Conduct responsible research
 - Ensure good stewardship of data
 - Promote transparency



Process for Sharing Data

When developing policies and procedures to guide access to clinical research data by external investigators, there are several key domains for consideration:

- Patient confidentiality
- Data management
- Data use
- Data storage

Patient Confidentiality

Protecting personal health information is of paramount importance

- Only data that can be appropriately de-identified should be shared
- Studies of rare diseases may have too few participants to prevent their de-identification
- Informed consent forms must allow sharing of de-identified data for public health benefit



Data Use

External investigators are required to sign a Data Use Agreement certifying that they will fulfill the following requirements:

- Requested data will not be used in pursuit of litigation or for commercial interests
- No distribution of the data to third parties or public posting of the data will be permitted
- The Principal Investigator (or any other permitted data user) will not attempt to re-identify individuals within the clinical trial data
- Initial dissemination of findings only through the peer-reviewed literature or scientific meetings

Data Management

Modest parameters were established to facilitate access while promoting transparency and responsible stewardship of data:

- External investigators required to register, submit a research proposal with request
- Proposal is reviewed by the YODA Project to ensure its scientific merit
- Further review can be solicited from Steering Committee or other peer experts
- All requests and associated registration materials, and the YODA Project's decision to grant or deny data access, are publicly posted



Data Storage

Data must remain protected and inaccessible by third parties.

- De-identified data can be housed on a secure server with encrypted access
 - Transfer these data directly to the requestor via the Yale FTP Site
 - Destroy all copies of the data at the end of a data use term
- De-identified data can be accessed via a password-protected personalized account on a secure data sharing platform
 - Work with these data within the secure platform only, without the ability to download or copy the data

Conclusion

- The YODA Project has developed a sustainable model to facilitate access to medical product manufacturers' clinical research data by external investigators
- The success of data sharing initiatives should be measured not by how many databases are made available but by how much useful knowledge is efficiently produced through their use and whether health and health care are improved as a result

